## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:.....3M ESPE AG
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ZIP-Code, City:.....D-82229 Seefeld
Federal State:.....Bavaria
Country:.....Germany
Establishment Registration Number.....9611385
Official Correspondent:.....Dr. Desi W. Soegiarto,
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Date:.....November 23, 2011

Name of Device

Proprietary Name:.....Heisenberg Effect Shades

Classification Name:.....Porcelain powder for clinical use

Common Name:.....Effect shade

Predicate Devices

Lava™ Frame Shade by 3M ESPE, Germany.....K011394
Zenostar Color Zr by Wieland Dental + Technik GmbH & Co. KG, Germany...K112710

Description for the Premarket Notification

Heisenberg Effect Shade is classified as Porcelain powder for clinical use (21 C.F.R. § 872.6660).

Heisenberg Effect Shades are suited for more intensive coloring of Heisenberg zirconia frameworks and Heisenberg all-zirconia, monolithic restorations for anterior and posterior teeth restorations after basic dyeing using Heisenberg Dyeing Liquids.

Heisenberg Effect Shades will be available in various colors.

Predicate devices to which Heisenberg Effect Shades have been compared are Lava™ Frame Shades by 3M ESPE, Germany (K011394) and Zenostar Color Zr by Wieland Dental + Technik, Germany (K112710). As Heisenberg Effect Shades, both predicate devices are suited to be used for coloring of zirconia restorations. Lava™ Frame Shades are suited to be used for the shading of zirconia frameworks and all-zirconia, monolithic restorations (made from Lava™ Frame zirconia mill blanks by 3M ESPE, K011394) for anterior and posterior teeth. As Heisenberg Effect Shades, Zenostar Color Zr Effect Shades are to be used for individual characterization of zirconia restorations.

In this 510(k) premarket notification Heisenberg Effect Shades have been compared to its predicate devices with regard to indications for use, physical and mechanical properties (data from bench testing), and chemical composition. The comparison for indications for use, performance data, and chemistry shows that Heisenberg Effect Shades are substantially equivalent to the predicate devices: Lava™ Frame Shades by 3M ESPE, Germany (K011394) and Zenostar Color Zr by Wieland Dental + Technik, Germany (K112710).

Biocompatibility testing was carried out. A biocompatibility assessment was developed for Heisenberg Effect Shades using standard risk assessment techniques and consideration of FDA & internationally recognized guidelines. The conclusion of the assessment is that Heisenberg Effect Shades are safe for its intended use.

In summary, it can be concluded that Heisenberg Effect Shades are as safe and effective as the predicate devices Lava™ Frame Shades by 3M ESPE, Germany (K011394) and Zenostar Color Zr by Wieland Dental + Technik, Germany (K112710).

Indications for Use:

Heisenberg Effect Shades are suited for more intensive coloring of Heisenberg zirconia frameworks and Heisenberg all-zirconia restorations after basic dyeing using Heisenberg Dyeing Liquids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

3M ESPE AG
C/O Mr. Norbert Stuiber
TUV SUD America Incorporated
1755 Old Highway 8 NW
New Brighton, Minnesota 55112

JAN 1 3 2012

Re: K120011
Trade/Device Name: Heisenberg Effect Shades
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 28, 2011
Received: January 3, 2012

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K120011

Device Name: Heisenberg Effect Shades

Indications For Use: Heisenberg Effect Shades are suited for more intensive coloring of Heisenberg zirconia frameworks and Heisenberg all-zirconia restorations after basic dyeing using Heisenberg Dyeing Liquids.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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